# Development of Patient Education Material for Proton Pump Inhibitor Deprescribing: A Mixed-Methods Study.

Jérôme Nguyen-Soenen, Maud Jourdain, Jean-Pascal Fournier

**ABSTRACT**

**Background:** Proton pump inhibitor (PPI) deprescribing is recommended in case of inappropriate use. Patient education materials are key elements in the deprescribing process. **Objective:** The study objective was to develop a patient education material for PPI deprescribing in primary care in France. **Methods:** Mixed methods study involving: i) a literature review of the existing patient education materials on PPI deprescribing to identify key points to optimize the layout and content of the document; ii) development of a first version of the brochure by a pluri-professional steering group following the national reference methodology of the French National Authority for Health (Haute Autorité de Santé) and iterative modifications of the patient brochure; iii) assessment of the content and understandability of the brochure by questionnaires followed by semi-structured interviews with target patients; and iv) iterative brochure readability assessment with the *Flesh reading ease* tool. **Results:** The final patient education material is a double-sided A3 brochure, *i.e.* four A4 pages. The first round of user testing by questionnaire (n=14 patients) led to modifications to improve the document understandability, validated in the second round of user testing by questionnaire (n=10 patients). The semi-structured interviews (n=10 patients) highlighted an adequate comprehension, whereas actionability required some minor modifications. The readability test score of the final education brochure was 59.4. **Conclusion and relevance:** This patient education brochure for PPI deprescribing is targeted to patients in primary care. Its impact on PPI deprescribing will be assessed in a population-based pragmatic trial in primary care.

**Keywords:** patient education material, primary care, deprescribing, proton pump inhibitors.

## BACKGROUND

Proton pump inhibitors (PPI) are one of the most commonly prescribed medications by general practitioners.[1] Worldwide, it is estimated that 25 to 70% of PPI prescriptions are inappropriate.[2] This rate is of 40% in France, and is most often related to an excessive duration of PPI use (>8 weeks).[3] Inappropriate use of PPI is associated with an increased risk of adverse kidney events (acute interstitial nephritis, chronic kidney disease)[4], adverse neurological events (dementia, hepatic encephalopathy)[5], and adverse cardiovascular events.[6] It is also associated with increased risk of *Clostridium difficile*-associated diarrhea, pneumoniae, and fractures.[7]

In France, primary care services are characterized by a gatekeeping system.[8] General practitioners are the first encounter of patients before possibly referring to other specialists. They coordinate patient care. As such, patient consultations with general practitioners may represent an opportunity to discuss prescribing habits.

Deprescribing is defined as the "process of withdrawal of an inappropriate medication, supervised by a healthcare professional with the aim of managing polypharmacy and improving outcomes".[9] Several deprescribing tools may be used in clinical practice: general deprescribing guidelines, medication-focused deprescribing frameworks, electronic clinical decision support systems, tools to identify potentially inappropriate medications, and tools for engaging patients.[10] Some tools have been specifically developed to facilitate the patient engagement in the process of shared decision-making concerning drug deprescribing[11,12], and some are targeted for PPI deprescribing.[13–15] However and to our knowledge, no such document has been developed in France yet. Moreover, a recent environmental scan of patient education materials for deprescribing reported that the available patient educational materials for deprescribing have inadequate readability levels for patients with limited health literacy.[16]

Therefore, the objective of our study was to develop and test a patient education material for PPI deprescribing adapted to primary care settings and to the French population.

## METHODS

This mixed-methods study integrated four phases in an explanatory sequential design (Figure 1): i) focused literature review, ii) development and iterative modifications of the patient brochure, iii) user testing by questionnaires followed by semi-structured interviews, iv) iterative brochure readability assessment evaluation. An explanatory sequential design was used to provide a comprehensive understanding of the problems and potential solutions arising during the material development and testing.[17,18]

### Literature review

A focused literature review on the available print and non-print patient education materials for PPI deprescribing and adapted to primary care settings was carried out and previously reported.[19] The suitability of the identified patient education materials was analyzed using the *Suitability Assessment of Materials* instrument.[20]

### Development of the first version of the patient information brochure

Our patient information brochure for PPI deprescribing was developed following two national reference guidelines of the French National Authority for Health (Haute Autorité de Santé, HAS)[21,22] and Santé Publique France.[23] A steering group involving different project stakeholders included two academic general practitioners, a primary care research coordinator, a biostatistician, two representatives of the local health insurance system (Caisse Primaire d'Assurance Maladie), and a graphist. The steering group created the different drafts that led to the first version of the patient education brochure. The group also developed a covering letter to be sent to patients with the brochure.

### User testing

*Questionnaire phase*

The brochure was first tested with target patients (*i.e.* patients using PPI for more than 8 weeks)[24] who were recruited in five primary care practices by general practitioners who were not involved in the study. At the end of the consultation, the general practitioners explained the objective of the user test (*i.e.* to evaluate the brochure layout and understandability). Patients who agreed to participate were given the version of the document to be tested and a printed questionnaire (Supplementary Material 1) developed following the HAS reference guideline.[22]

If the results of the first user testing round led to significant changes to the brochure design/content, a second user testing round was planned to assess the new version of the brochure using the same questionnaire. For each testing round, approximately 10 patients were sought, in line with similar procedures used to develop medication package leaflets for patients and French guidelines.[21,22,25]

*Semi-structured interviews phase*

A qualitative analysis using semi-structured interviews was carried out with additional target patients. An opportunistic sample of primary care patients using PPI for more than 8 weeks was constituted, with attention to variation in age, sex, and educational level. These patients were invited to participate to the interviews by their general practitioners. Quantitative data from questionnaire phase were integrated using a building approach. The research team elaborated an interview guide (Supplementary Material 2), based on the points identified as requiring a more in-depth analysis on the basis of the patients' feedback in the questionnaire phase. Face-to-face interviews were performed by the three researchers. The interviewers and participants did not know each other before the start of the study. Interviews were recorded, transcribed verbatim, and coded manually using an iterative procedure by each researcher. A thematic analysis was carried out and was independently reviewed by one of the researchers (MJ) who was not involved in the study conception.

Additional changes were introduced in the brochure if necessary.

**Readability test**

The readability of each version of the patient education brochure was assessed using the *Flesch Reading Ease* formula that allows estimating the school level needed to understand a document correctly.[26] The score is calculated on the basis of the number of sentences, words and syllables. A score between 90 and 100 corresponds to the "primary school" level, a score between 60 and 90 to the "junior secondary school" level, a score between 50 and 60 to the "senior secondary school" level, and a score lower than 50 to the "higher education" level. The *Suitability Assessment of Materials* instrument deems a score superior to 60 as "satisfactory".[20] The objective for the brochure was to achieve a score of at least 60.

## RESULTS

The study was carried out between November 2018 and June 2021. The successive versions of the patient education brochure for PPI deprescribing and the changes introduced on the basis of the patients' feedback are presented in Supplementary Material 3.

### Literature review

The literature review was carried out from November 2018 to April 2019 and the results were reported previously.[19] Briefly, seven patient education materials on PPI deprescribing were identified. Several weaknesses of these materials allowed focusing particularly on the following points for the brochure design: readability, layout, and inclusion of a take-home message.

### Development of the first version of the patient education brochure

The first version of the patient education brochure was developed between June 2019 and August 2019. Four drafts were proposed and revised. A version was selected by consensus by the steering group to be tested with patients. This patient education brochure was a double-sided A3 document (*i.e.* four A4 pages), and included six sections:

i) "Do I still need to take my treatment for reflux and heartburn?" where readers are asked to identify the PPI they were using and to report duration of use and indication;
ii) "Why are these medications prescribed?" where PPI pharmacodynamics and their validated indications are described;
iii) "What are the risks associated with these medications?" where PPI adverse events are described;

iv) "What else can I do for my reflux and heartburn?" where diet and lifestyle modifications and alternative medications are described;

v) "What should I discuss with my general practitioner?" where readers are invited to meet their general practitioner for a discussion on PPI deprescribing and its implementation, if needed;

vi) Take-home message.

**User testing by questionnaire**

*First user testing round*

The first user testing round was carried out between December 2019 and January 2020 (n=14 patients, Table 1). At the end of this first round, minor changes were introduced to improve understanding: i) modification of the brochure title to focus on PPI medications rather than on PPI indications (moved to the subtitle), ii) addition of the last revision date, and iii) explanation of the PPI acronym in each page.

*Second user testing round*

The second testing round was carried out in February 2020 (n=10 patients, Table 1). The second round did not lead to any additional modification. "Ranitidine" was replaced by "Cimetidine" due to its suspension in France between the first and the second version of the brochure.[27]

**Semi-structured interviews**

Ten semi-structured interviews were carried out from June 2020 to June 2021. The participants' mean age was 65±13.8 years (n=3 women and n=7 men, Supplementary Material 4). Data saturation was achieved, as no additional data emerged for participants 9 and 10. Participants reported positive feelings upon receiving and reading the brochure,

with the exception of one person who expressed mistrust concerning the process of deprescribing that in his opinion, would serve the interests of pharmaceutical industries (participant 2, P2).

The semi-structured interviews supported the document actionability. All interviewees showed interest in the interview, despite the ongoing COVID-19-related health crisis: “I fully agree to receive this type of document to help medicine” (P3), although one participant said that he did it to “please [his] doctor” (P6).

Others did not spend much time discussing the brochure layout and understanding, but rather focused on their personal history with PPI and their health conditions. They described their experience or fear about PPI discontinuation: “it was negative to reduce it because I had reflux, I was in a lot of pain, so in fact I didn't reduce it” (P3), “it's like having my stomach pinched” (P4); and their worries about adverse reactions: “we heal on one hand, to get pain on the other hand” (P7), “it is the increased risk of pulmonary and intestinal infections that disturbed me the most” (P8). In conclusion, the interview analysis suggested that the brochure could be an effective tool to engage the discussion on PPI with a healthcare professional.

The interviews led to minor modifications on the layout of the patient education brochure:

- reorganization of the paragraphs to improve the reading experience and understandability;
- minor modification of the take-home message “I take an appointment with my general practitioner to talk about PPI deprescribing”, to highlight the need of discussing PPI deprescribing with a healthcare professional;
- the term “proton pump inhibitor” was not known by all patients: “I had never heard of proton pump inhibitors [...] I always talked about heartburn or acid reflux” (P1). It was maintained, but its meaning was better explained.

A minor modification was introduced in the covering letter to increase actionability, by adding a summary sentence to stress that patients may take an appointment with their

general practitioner: “We invite you to take an appointment with your general practitioner and to bring this brochure with you on that occasion”.

**Readability test**

The *Flesch Reading Ease* test score of the initial education brochure was 59.1. The score was 59.2 after the questionnaire phase. The score of the final education brochure was 59.4.

## DISCUSSION

The development, testing and revision of a patient education material for PPI deprescribing led to the finalization of an A3 brochure, folded in two (thus four A4 pages, Figure 2) with its covering letter (Figure 3).

The existing patient education materials for PPI deprescribing allow increasing the patient knowledge on their medication and on alternative approaches. Their aim is to invite patients to discuss with a healthcare professional the possibility of discontinuing or decreasing the dose of a potentially inappropriate medication. Several studies supported the effectiveness of such patient education materials for deprescribing. In 2015, Clyne et *al.* reported that a multifaceted intervention involving patient education materials for deprescribing might reduce potentially inappropriate prescriptions in primary care by 48%.[13] In 2017, Pratt et *al.* showed that the multifaceted Australian national quality improvement programs including patient educational material contributed to PPI use decrease by older adults by 21%.[14] In the trial EMPOWER, sending a patient educational brochure led to 35% of successful deprescribing outcomes among chronic benzodiazepine users, when they were supported by a healthcare professional.[15] However, the methods used to develop these patient education materials were seldomly described, thus limiting the understanding of the mechanisms underlying the effectiveness and weaknesses of these tools, and the possibilities of future adaptations.

Our patient education brochure has several purposes. First, it is the key element of a PPI deprescribing intervention that will be assessed in the pragmatic 3-arm cluster randomized trial "DeprescrIPP" (ClinicalTrials.gov identifier: NCT04255823). The brochure will be sent by post to the patients in the "multifaceted intervention" arm, with the covering letter to increase actionability. Moreover, the general practitioner of patients in the "multifaceted intervention" arm will receive by post the PPI deprescribing algorithm developed by the Bruyere Research Institute research group.[28] The study will include also a second arm in which only the general practitioner will receive the algorithm, and a third control arm with

no intervention. If the effectiveness of the patient education brochure for PPI describing is supported by this trial, then its use could be extended to pluri-professional PPI deprescribing protocols in primary care. Moreover, its implementation could be envisaged nationwide by the French health insurance system.

**Strengths**

First, the brochure was developed using a methodology similar to what used for the drug package leaflets for patients described by Raynor *et al.* in 2013 in which a quantitative approach by questionnaire was completed with a qualitative approach using semi-structured interview.[25]

Second, multi-center user testing rounds were organized by recruiting target patients in the offices of general practitioners not implicated in this research project. This ensured the diversity of patient testers.

Third, the semi-structured interviews highlighted some issues in the text layout and understandability that were not detected using the questionnaires. Semi-structured interviews ensured a response exhaustivity on the issues that were important to the researchers. Moreover, they showed that patients were keen to discuss their treatments with healthcare professionals.

**Weaknesses**

First, for practical and financial reasons, the two testing rounds were not carried out in the same conditions as the final use of the patient education brochure (*i.e.* delivery by post to the patients). However, the patient testers corresponded to the target population of the "DeprescrIPP" trial and they discovered and read the brochure on their own without any explanation by a healthcare professional.

Second, in the absence of international guidelines on the development of patient education materials, we followed the French guidelines for the testing and validation rounds.[22,23] We

also took into account other methodologies described in the international literature.[29,30] As to our knowledge, there is no PPI user organization in France, the testing and content revision steps were performed with patients recruited by general practitioners.

Third, we wanted to keep the recruitment process to the simplest in order to have as little impact as possible on daily activities of participating general practitioners. During questionnaire phases, we did not collect detailed characteristics on patients. Participation refusal was also not formally notified, though, to our knowledge, all patients approached agreed to participate.

Fourth, although we have conducted our tests on end-users only (in relation with the context of the postal brochure sending in the "DeprescrIPP" trial), one should consider extending testing to other primary care stakeholders (including general practitioners, community pharmacists, nurses and patients' relatives) before considering extending the use of the brochure to other contexts.

Finally, although several simplifications of the brochure content led to progressive increase in the readability score, we could not increase the readability score above the score corresponding to the "junior secondary school" level. This readability score is relatively satisfactory compared with those of other patient education materials.[16,19] This score is calculated solely on words and sentence used and does not take into account other factors that affect comprehension (e.g. illustrations, grammatical choices or layout). Nevertheless, it may limit the correct use of the document by populations with low literacy.

## Conclusion and relevance

The development of a patient education brochure for PPI deprescribing is a key step in our pragmatic trial "DeprescrIPP" on PPI deprescribing in primary care. If its effectiveness is supported, the brochure could be used in the framework of a multi-professional deprescribing protocol, implemented nationwide, and also adapted to other drugs.

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## TABLES

### Table 1: Results of the first and second user testing rounds by questionnaire

| Item response [a] | "Rather yes" or "Yes" | |
|---|---|---|
| | Round 1 (n=14) | Round 2 (n=10) |
| **Understanding of the main message** | | |
| Is the main message clear? | 5 (35.7%) | 4 (50.0) |
| **Attractiveness of the brochure** | | |
| Did you like the figures? | 13 (92.9) | 10 (100) |
| Do these figures help to better understand the text? | 14 (100) | 8 (88.9) |
| Does the layout make you feel like reading the brochure? | 13 (92.9) | 9 (90.0) |
| **Trustworthiness of the brochure** | | |
| Do you think that the sources and references are reliable? | 14 (100) | 8 (80.0) |
| Do you trust the institutions that funded the brochure production? | 8 (88.9) | 3 (60.0) |
| Is the date of the version of the brochure visible? | 2 (14.3) | 6 (85.7) |
| Do you feel like talking about this brochure to your family and friends? | 10 (90.9) | 7 (77.8) |
| **Free text** | | |
| Positive points | Simple (8)<br>Layout (5) | Illustrations (2)<br>Explanations (2)<br>Clarity (1)<br>Simple and effective (1)<br>Pagination (1) |
| Negative points | PPI acronym not understood (1)<br>Blaming message (1) | |

[a]Values are presented as n (%). Missing answers were not counted.

**FIGURE**

**Figure 1.** Phases of the mixed-methods study

**Figure 2.** Final version of the patient education brochure for PPI deprescribing

**Figure 3.** Covering letter